

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P., and DEY, INC.,

Defendants.

C.A. No. 06-113-JJF

C.A. No. 06-604-JJF

CONSOLIDATED

**THIRD AMENDED STIPULATED PROTECTIVE ORDER**

WHEREAS discovery in this action may involve the disclosure of certain documents, things and information in the possession, custody or control of the plaintiff, Sepracor Inc. ("Sepracor"), the defendants, Dey, L.P. and Dey, Inc. ("Dey"), or non-parties, and that constitute or contain trade secrets or other confidential research, development or commercial information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS such confidential information must be protected in order to preserve the legitimate business interests of the parties or non-parties;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order for the purpose of advancing the progress of this case and to prevent unnecessary dissemination or disclosure of such confidential information; and

WHEREAS the parties have established good cause for entry of this Protective Order;

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in this action:

Definitions

1. The term “Confidential Information” shall mean any document, information, data, or other tangible thing, or oral testimony that contains or reveals what a party or non-party considers to be its trade secret, business confidential, or proprietary information. In designating information as “Confidential Information,” a party or non-party shall designate only its trade secrets, information that it has maintained in confidence, or information in which it has a proprietary interest. Each party shall act in good faith in designating information as “Confidential Information.”

2. The term “Qualified Person” shall mean:

- (a) the Court and its official personnel;
- (b) Sepracor’s outside counsel of record in Case No. 06-113-JJF and Case No. 06-604-JJF, and their law firms’ active members, associate attorneys, paralegals, and office staff working on this case (“Sepracor’s Outside Counsel”);
- (c) Dey’s outside counsel of record in Case No. 06-113-JJF and Case No. 06-604-JJF, and their law firms’ active members, associate attorneys, paralegals, and office staff working on this case (“Dey’s Outside Counsel”);
- (d) court reporters, translators, third-party photocopy or imaging services contractors, third-party contractors producing graphic or visual aids involved solely in providing litigation support services to Outside Counsel;
- (e) any independent expert or consultant who is retained by Sepracor’s or Dey’s Outside Counsel subject to the provisions of paragraph 11, and solely for the purpose of assisting in this action;
- (f) (i) Two in-house attorneys for Sepracor, namely Andrew I. Koven and Matthew P. Blischak , and their clerical or legal assistant employees whose

functions require access to Confidential Information, all of whom, after receipt of Dey Confidential Information and in addition to the other terms of this Protective Order, (A) shall not be involved in the preparation or prosecution of any patent application that covers XOPENEX® described in New Drug Application (“NDA”) No. 20-837 or Dey’s generic version of XOPENEX® described in Abbreviated New Drug Application (“ANDA”) No. 77-800 for the duration of the action including any appeals, and (B) shall not use Dey’s Confidential Information to prepare or prosecute any future or pending patent application for Sepracor.

(ii) Two in-house attorneys for Dey, Joseph F. Haggerty and Jill M. Ondos, and their clerical or legal assistant employees whose functions require access to Confidential Information, all of whom, after receipt of Sepracor Confidential Information and in addition to the other terms of this Protective Order, (A) shall not be involved in the preparation or prosecution of any patent application that covers XOPENEX® described in New Drug Application (“NDA”) No. 20-837 or Dey’s generic version of XOPENEX® described in Abbreviated New Drug Application (“ANDA”) No. 77-800 for the duration of the action including any appeals, and (B) shall not use Sepracor’s Confidential Information to prepare or prosecute any future or pending patent application for Dey.

(g) any other person who is designated as a “Qualified Person” by order of the Court or by written agreement of the parties.

Use of Confidential Information

3. Confidential Information shall be used solely for the purpose of this action.

4. Nothing in this Protective Order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Confidential Information if such information:

- (a) was lawfully in his or her possession prior to receipt under the provisions of this Protective Order;
- (b) was or becomes available to the public through no fault of a receiving party;
- (c) was or is obtained from a source not under an obligation of secrecy to the designating party; or
- (d) is exempted from the operation of this Protective Order by written consent of the designating party.

Disclosure of Confidential Information

5. Confidential Information shall not be made available to anyone other than a Qualified Person or the party who produced such Confidential Information, except as otherwise provided in this Protective Order.

6. A document that contains or reveals Confidential Information may be shown to any person indicated in such document to be its originator or author or the recipient of a copy.

7. As set forth in paragraph 2(d), a document that contains or reveals Confidential Information may be copied by an independent commercial copying service, and an exhibit based upon such a document may be prepared by an independent printer or illustrator. Any exhibit(s) so prepared shall be treated as Confidential Information.

8. Confidential Information may be disclosed to a witness testifying under oath if the witness is an officer, director, or employee of the party who produced such Confidential Information.

9. Confidential Information may be disclosed to a witness testifying under oath if:

- (a) the witness was formerly an officer, director, or employee of the party who produced such Confidential Information;
- (b) the Confidential Information was in existence during the period of his or her service or employment; and
- (c) a foundation is established that the witness was involved in the project to which the Confidential Information relates so that it is reasonable that the witness had access to the Confidential Information during the course of his or her service or employment.

10. Nothing in this Protective Order shall prevent disclosure of Confidential Information if the designating party consents to such disclosure or if the Court, after notice to all parties, orders such disclosure.

11. (a) Counsel desiring to disclose Confidential Information to an independent expert or consultant according to paragraph 2(e) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person. At least ten (10) days in advance of the proposed disclosure of any Confidential Information to that person, counsel shall serve that person's signed declaration, a curriculum vitae or resume, a general statement of any prior or current relationship or connection with either party, and a list of all cases in which such person has been deposed or testified as an expert for

the preceding four (4) years by facsimile on each other party. A party may object for cause to the proposed disclosure by serving a written objection upon each other party within seven (7) days after receiving the copy of the signed declaration and other materials by facsimile. Failure to timely object shall operate as a waiver of the objection. If a party objects to the proposed disclosure, the objecting party's Confidential Information shall not be disclosed to such person except by order of the Court or by written consent of the objecting party. In the event that a motion is made, the objecting party shall have the burden of proving that disclosure should not be made and any such motion shall be filed no later than fourteen (14) days after the objections are made. A party shall not attempt to make any contact with, including but not limited to deposing, any person whose declaration has been served by another party pursuant to this paragraph regarding their work or the opinions formed as an expert, investigator, consultant or advisor for the other party serving the declaration, unless an expert report written pursuant to Fed. R. Civ. P. 26 has been served. Nothing in this paragraph shall preclude a party from contacting fact witnesses directly or, if the fact witness is represented through counsel.

(b) Counsel desiring to disclose Confidential Information to a person according to paragraphs 2(f), and/or 2(g) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person.

Identification and Marking of Confidential Information

12. Any document or other tangible thing that contains or reveals Confidential Information shall be labeled with the legend "CONFIDENTIAL INFORMATION UNDER PROTECTIVE ORDER" or a marking of like import. For a document, such marking shall appear on each page of the document that contains Confidential

Information. Any document or other tangible thing so labeled and the information it contains or reveals shall be treated in accordance with the provisions of this Protective Order. Any Confidential Information not reduced to documentary or physical form or which cannot be conveniently labeled shall be so designated by a party by serving a written notification on the receiving party.

13. When a party initially produces documents for inspection by a Qualified Person, no marking need be made by the producing party in advance of the inspection. For purposes of the inspection, all documents shall be treated as containing Confidential Information. After the receiving party selects specified documents for copying, the producing party shall appropriately mark the copies of the selected documents before they are provided to the receiving party.

14. Information disclosed in a deposition may be designated as Confidential Information by a party or by the non-party giving the deposition either (a) on the record at the deposition or (b) by serving a written notification on all parties and, if applicable, the non-party who gave the deposition, within fourteen (14) days of the date on which the deposition transcript becomes final, either by completion and service of an errata sheet or passage of the time allowed for doing so, whichever first occurs. Such written notification shall identify the specific pages and lines of the transcript that contain Confidential Information. A copy of such written notification shall be attached to the face of the transcript and each copy of the transcript in the possession, custody, or control of any Qualified Person. Until the transcript becomes final, either by completion and service of an errata sheet or passage of time allowed for doing so, whichever first occurs,

all information disclosed during any deposition shall be treated as Confidential Information.

15. Only Qualified Persons, the deponent, and the court reporter shall be allowed to attend any portion of a deposition in which Confidential Information is used or elicited from the deponent.

16. Deposition transcripts containing testimony with Confidential Information shall be prominently marked on the front page with a statement that provides "THIS DEPOSITION TRANSCRIPT CONTAINS CONFIDENTIAL INFORMATION THAT IS SUBJECT TO PROTECTIVE ORDER." Except as to experts, all such deposition transcripts shall also be prominently marked on the front page with a statement that provides "Deponents shall not retain or copy portions of the transcript of their depositions that contain Confidential Information not provided by them or entities they represent."

Inadvertent Production

17. The inadvertent failure by a producing party to designate specific documents or materials as containing Confidential Information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. Upon notice to the receiving party of such failure to designate, the receiving party shall cooperate to restore the confidentiality of the inadvertently disclosed information.

18. Inadvertent production of documents or information subject to the attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not constitute a waiver of such privilege(s). Inadvertent production of documents or information shall be handled as follows, but is without prejudice to the right of any party to apply to the Court for further protection or disclosure relating to discovery:

(a) Immediately upon receiving notice from the producing party that documents or materials subject to the attorney-client privilege or work-product immunity have been inadvertently produced, the receiving party shall, except to the extent necessary to challenge the privilege claim pursuant to paragraphs 18(b)-(c), not review, copy, or otherwise disseminate the documents or materials, nor shall it disclose their substance. In addition, the receiving party shall return the documents or materials and all copies or certify they have been destroyed within ten (10) days from receiving notice.

(b) If the receiving party believes it has a good-faith basis for challenging the privilege claim, Outside Counsel for the receiving party shall provide the Outside Counsel for the producing party with a written explanation of the good-faith basis for its belief that the inadvertently produced documents or information are not privileged within fourteen (14) days after receipt of the producing party's request for return.

(c) Outside Counsel for the producing party shall respond in writing to receiving party's Outside Counsel's timely challenge to the privilege or immunity claim within seven (7) days from receipt of the challenge.

(d) In the event the parties cannot agree as to the privilege or immunity status of the inadvertently produced documents or materials, the receiving party has fourteen (14) days from receipt of the producing party's written response to the privilege challenge to file a motion seeking an order compelling production of the inadvertently produced documents or information. In the event that a motion is made, the producing party shall have the burden of proving that the produced documents or information are privileged. To the extent the substantive content of the inadvertently

produced documents or information is used in or with a motion to challenge the privilege or immunity status of such material, such material shall be treated as Confidential Information.

(e) Within five (5) days of the receiving party's timely filing of a motion seeking an order compelling production of the inadvertently produced documents or information subject to the attorney-client privilege, work product immunity, or any other applicable privilege or immunity, the producing party shall file under seal with the Court a copy of the inadvertently produced documents or information for in camera inspection by the Court. A copy of the cover letter forwarding the inadvertently produced documents or information for in camera inspection by the Court shall be provided to the moving party.

Challenges to Confidential Information Designation

19. A party shall not be obligated to challenge the propriety of a Confidential Information designation at the time made, and a failure to do so shall not preclude a subsequent challenge thereto.

(a) In the event that a party disagrees at any time with a Confidential Information designation made by another party, the following procedure shall be used: The party seeking such removal shall give Outside Counsel for the designating party or non-party notice thereof, in writing, specifying the documents, things, or information for which such removal is sought and the reasons for the request. The designating party or non-party shall have fourteen (14) days after receiving that written notification within which to object to the removal of protection afforded by this Order. Any such objection shall be made in writing. Failure to object within the requisite time limit is deemed a

waiver of any claim to protection for that specific document, thing, or information under this Protective Order.

(b) If, after conferring in good faith, the parties, or the parties and non-party, cannot reach agreement concerning the matter, then the party or non-party seeking the removal of protection for the designated Confidential Information shall follow the Court's procedures for discovery disputes as set out in paragraph 3(f) of the Rule 16 Scheduling Order entered in this matter. The designated material shall continue to be treated as Confidential Information until the issue is resolved by Order of this Court or by agreement of the parties, or the parties and non-party.

(c) On any motions arising out of the designation of any material as Confidential Information under this Protective Order, the burden of justifying the designation shall lie with the designating party or non-party.

Improper Disclosure

20. If any designated material is disclosed to any person contrary to the terms of this Protective Order or other than in the manner authorized by this Protective Order, Outside Counsel of the party learning of the disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of the producing party, and without prejudice to the rights and remedies of the producing party, make every effort to retrieve the improperly disclosed material and to prevent further unauthorized disclosure on its own part and further unauthorized use and disclosure on the part of the recipient of such information or material.

Third Party Designations

21. Where a subpoena, deposition question, or discovery request directed to a party or non-party who is designating Confidential Information under this Protective

Order calls for otherwise discoverable information that is held by such party or non-party to whom it is directed under obligations of confidentiality owed to another, and the party or non-party to whom the subpoena, deposition question, or discovery request is directed refuses to provide such documents or information on that ground, that party or non-party:

(a) Shall promptly identify to the party seeking the documents or information the name and address of each person or entity whose confidentiality interests are implicated by the subpoena, deposition question, or discovery request and the basis for the obligation of confidentiality, including a copy of any relevant protective order;

(b) Shall promptly notify the person or entity whose confidentiality interests are implicated by the subpoena, deposition question, or discovery request so that the person or entity may have an opportunity to appear and be heard on whether the information should be disclosed.

Filing of Confidential Information

22. The Clerk of the Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, as containing or revealing Confidential Information.

23. In the event that a party wishes to use any Confidential Information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court, such paper shall be enclosed in a sealed envelope or other appropriate container. The sealed envelope or other appropriate container shall:

- (a) show the caption of this action;
- (b) identify its contents; and

(c) include the following legend:

CONFIDENTIAL INFORMATION

This envelope [or container] is sealed pursuant to court order and contains proprietary information. This envelope [or container] was filed by [name of party] and may not be opened, nor may its contents be displayed or revealed, except by court order or by written stipulation of the parties.

Advice to Clients

24. Nothing in this Protective Order shall bar or otherwise restrict an attorney who is a Qualified Person from rendering advice to his or her client with respect to this action and, in the course thereof, referring to or relying upon his or her examination of Confidential Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any Confidential Information if such disclosure would be contrary to the provisions of this Protective Order.

Miscellaneous

25. No party shall be responsible to another party for any use made of information that was produced and not designated as Confidential Information.

26. Nothing in this Protective Order shall prejudice the right of any party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

27. Nothing in this Protective Order shall prejudice the right of any party to seek at any time a further order modifying this Protective Order.

28. In the event that a new party is added, substituted, or brought in, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.

29. Nothing in this Protective Order shall prejudice the right of any party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any Confidential Information.

30. By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Protective Order who becomes subject to a subpoena, motion, governmental or administrative agency request, or order to disclose such information, documents or things designated as Confidential Information by another party pursuant to the Protective Order shall promptly (but in no event later than ten (10) days after receiving said subpoena, motion, governmental or administrative agency request, or order) notify the designating party of the subpoena, motion, governmental or administrative agency request, or order so that the designating party may have an opportunity to appear and be heard on whether the information should be disclosed.

31. Within ninety (90) days after the termination of this litigation (including any appeals), each document and each other tangible thing that contains or reveals Confidential Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Confidential Information shall be either: (a) returned to the attorney of record for the producing party; or (b) destroyed with a representation of such destruction being made to the attorney of record for the producing party. Notwithstanding the foregoing, outside counsel for a receiving party may retain Confidential Information to the extent such Confidential Information is contained in counsel's work product, correspondence between outside counsel, or in copies of

pleadings and materials that are of record in the litigation, subject to the confidentiality provisions of this Protective Order.

32. Within ninety (90) days after the termination of this litigation (including any appeals), any Confidential Information that was filed under seal with the Clerk of the Court shall be returned to the attorney of record for the filing party.

33. Time periods referred to herein shall be calculated in accordance with Fed. R. Civ. P. 6.

34. The provisions of this Protective Order shall survive and remain in full force and effect after the termination of this litigation (including any appeals).

35. Any notice under this Protective Order shall be by facsimile and e-mail to the parties as follows, unless this provision is modified by the parties in writing and filed with this Court: notice to Sepracor shall be made to Jack B. Blumenfeld, Joseph M. O'Malley Jr., and Preston K. Ratliff II; notice to Dey shall be to John Day, Elizabeth A. Leff, and Kimberly McGraw, all at their respective offices of record filed with this Court for this civil action.

**SO ORDERED:**

Dated: \_\_\_\_\_

Hon. Joseph J. Farnan, Jr.  
United States District Judge

**SO STIPULATED AND AGREED TO:**

OF COUNSEL:

Joseph M. O'Malley, Jr.  
Bruce M. Wexler  
Preston K. Ratliff, II  
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MORRIS, NICHOLS, ARSHT &  
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*/s/ Karen Jacobs Louden*

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**EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P. and DEY, INC.,

Defendants.

C.A. No. 06-113-JJF  
C.A. No. 06-604-JJF  
CONSOLIDATED CASES

**DECLARATION**

I, \_\_\_\_\_, being duly sworn, declare as follows:

1. My home address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_ and the address of my present employer is \_\_\_\_\_.
3. My present occupation or job description is \_\_\_\_\_.
4. I have carefully read and understand the provisions of the Second Amended Stipulated Protective Order in this case approved by the U.S. District Court, and I will comply with and agree to be bound by all of the provisions of the Third Amended Stipulated Protective Order.
5. I will hold in confidence and not disclose to anyone any Confidential Information or any words, summaries, abstracts or indices of Confidential Information disclosed to me, except in accordance with the Third Amended Stipulated Protective Order.
6. I shall not use or refer to any of the documents, things, and/or any information designated under the Third Amended Stipulated Protective Order other than in

connection with this litigation and as prescribed in the Third Amended Stipulated Protective Order.

7. Upon notification that this litigation has terminated, or at such earlier time as requested by the counsel or party by whom I am employed or retained, I will return all documents and things designated as containing Confidential Information, and all summaries, abstracts and indices thereof, which come into my possession, and documents or things which have been prepared relating thereto, to counsel for the party by whom I am employed or retained.

8. I do and shall subject myself to the continuing jurisdiction of the above-entitled Court over my person, wherever I shall be found, for purposes of enforcement of the Third Amended Stipulated Protective Order.

9. I declare under penalty of perjury that the foregoing is true and correct.

By: \_\_\_\_\_

Dated: \_\_\_\_\_

Subscribed and sworn to before me  
this \_\_\_\_ day of \_\_\_\_\_, 200\_\_\_\_.

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Notary Public  
My Commission Expires: